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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Mark S. Ortiz	: Paper No:	
Serial No.	10/675,705	: Group Art Unit:	3743
Filed:	September 30, 2003	: Examiner:	Natalie R. Pous

For: SINGLE LUMEN ACCESS DEPLOYABLE RING FOR INTRALUMENAL ANASTOMOSIS

Confirmation No. 6304

AMENDMENT AND RESPONSE

MS Amendment
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, dated February 27, 2006, please amend the above-identified patent application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims begin on page 3 of this paper.

Remarks begin on page 7 of this paper.

AMENDMENT

Amendments to the Specification

Please substitute the following for Para. 0001:

[0001] The present application is related to four co-pending and commonly-owned application filed on even date herewith, the disclosure of each is hereby incorporated by reference in its entirety:

"Anastomosis Wire Ring Device", Serial No. 10/674,371 to Don Tanaka, Mark Ortiz and Darrel Powell;

"Applier For Fastener For Single Lumen Access Anastomosis", Serial No. 10/675,077 to Mark Ortiz;

"Unfolding Anastomosis Ring Device", Serial No. 10/675,091 to Jean Beaupre; and

"Single Lumen Anastomosis Applier for Fastener", Serial No. 10/675,497 to Mark Ortiz, Robert McKenna, Bill Kramer, Mike Stokes, and Foster Stulen.

Amendments to the Claims

1. (currently amended) An anastomosis device, comprising:

a proximal ring;

a distal ring;

a plurality of proximal arms each attached to the proximal ring at one end and having a distally directed other end;

a plurality of distal arms attached to the distal ring at one end and having a proximally directed other end;

a center portion coupling the proximal end of each distal arm to the distal end of each proximal arm; and

a latching mechanism operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center portion;

wherein the anastomosis device comprises a polymer biofragmentable material and forms a cylindrical shape when unactuated and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape.

2. (Original) The anastomosis device of claim 1, wherein the center portion comprises a center ring aligned and interposed between the proximal and distal rings.

3. (Original) The anastomosis device of claim 2, wherein the proximal arms are radially aligned with the distal arms

4. (Original) The anastomosis device of claim 2, wherein the proximal arms are radially staggered with the distal arms to form a tortuous path of apposed tissue.

5. (Original) The anastomosis device of claim 1, further comprising radiopaque target material.

6. – 7. (canceled)

8. (Original) The anastomosis device of claim 1, wherein the device is formed from sheet material, cylindrically formed onto a mandrel, and opposing longitudinal edges attaches one to another.

9. (Original) The anastomosis device of claim 1, wherein the latching mechanism comprises at least one interiorly disposed hook.

10. (Original) The anastomosis device of claim 1, wherein the latching mechanism comprises an interference fit formed between rings.

11. (Original) The anastomosis de vice of claim 1, wherein the proximal and distal arms each include a hinge.

12. (Original) The anastomosis device of claim 11, wherein the central disposed hinge of each arm defines an inner arm segment and an outer arm segment, further comprising a pad outwardly disposed on each inner arm segment.

13. – 20. (canceled)

21. (new) An anastomosis device, comprising:

a proximal ring;

a distal ring;

a plurality of proximal arms each attached to the proximal ring at one end and having a distally directed other end;

a plurality of distal arms attached to the distal ring at one end and having a proximally directed other end and radially staggered with the plurality of proximal arms to form a tortuous path of apposed tissue;

a center ring aligned and interposed between the proximal and distal rings and coupling the proximal end of each distal arm to the distal end of each proximal arm; and

a latching mechanism operably configured to lock, at a reduced longitudinal spacing, two selected rings from a group consisting of the proximal ring, the distal ring, and the center ring;

wherein the anastomosis device forms a cylindrical shape when unactuated and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape.

22. (new) The anastomosis device of claim 21, wherein the proximal and distal arms each include a hinge, the central disposed hinge of each arm defines an inner arm segment and an outer arm segment, the anastomosis device further comprising a pad outwardly disposed on each inner arm segment.

23. (new) A method of forming an anastomosis device, comprising:

forming a generally rectangular substrate having a distal portion;

forming a proximal plurality of longitudinal and laterally spaced separations defining a proximal arm portion;

forming a distal plurality of longitudinal and laterally spaced separations defining a distal arm portion, leaving a distal lateral band, a central lateral band, and a proximal lateral band;

shaping the substrate into a cylinder about its longitudinal axis; and

connecting opposite lateral edges.

24. (new) The method of forming an anastomosis device of claim 23, wherein forming the generally rectangular substrate further comprises forming from a biofragmentable material.

25. (new) The method of forming an anastomosis device of claim 23, further comprising adding a radiopaque material to the substrate.

26. (new) The method of forming an anastomosis device of claim 23, wherein forming the generally rectangular substrate further comprises forming from a metal sheet material.

27. (new) The method of forming an anastomosis device of claim 23, wherein connecting opposite lateral edges comprises fusing.

28. (new) The method of forming an anastomosis device of claim 23, further comprising forming laterally aligned hinge portions in both the proximal and distal arm portions.

29. (new) The method of forming an anastomosis device of claim 23, wherein the hinge portion of each arm defines a longitudinally shorter inner arm segment from a longer outer arm segment, further comprising forming a plurality of separations in the center portion, each of the plurality of separations communicating between a pair of aligned separations respectively in the proximal and distal arm portions to allow the center portion to dilate when actuated.

30. (new) The method of forming an anastomosis device of claim 23, wherein the proximal plurality of separations are laterally offset from the distal plurality of separations to form staggered proximal and distal arms.

31. (new) The method of claim 23, further comprising forming lateral indentions on an undersurface of the generally rectangular substrate to form hinge points.

32. (new) The method of claim 23, further comprising attaching a pad to a central portion of each arm.

REMARKS

In the subject Office action dated 27 February 2006, claims 1-20 were examined. In response thereto, claim 1 is amended, claims 6, 7 and 13-20 are canceled, claims 21-32 are new, and claims 2-5 and 8-12 remain under active prosecution. Applicant asserts that the claims are supported by the Specification as originally filed and do not introduce new subject matter.

Applicant appreciates notice by the Examiner that a cross reference to related applications has not yet been amended to reflect the later assigned serial numbers. Applicant has amended the first paragraph of the Specification to add the serial numbers of four commonly-owned applications filed on the same day as the present invention and incorporated by reference.

With regard to an objection to the drawings, Applicant hereby is submitting formal drawings annotated as Replacement Drawings to replace the informal drawings originally filed.

Turning to the substantive rejections in the subject Office action, Claims 1-3, 6, 7, 9-11 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch. Claims 8, 13 and 16-19 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huebsch et al (US 5,853,422). Claims 4, 5, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Berg (US 6,712,836). Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Barra et al. (US 5843088).

Turning to independent claim 1, the claim has been amended to include the additional features of claims 6 and 7 and thus recites in part an anastomosis device comprised of a biofragmentable material which forms a cylindrical shape when unactuated and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape.

The Examiner rejected claim 7 as anticipated by US 5,853,422 Huebsch et al, relying upon Huebsch as teaching an anastomosis device of FIG. 4 formed from polymer material (Column 2, proximate lines 23-28) that is further a biofragmentable material (Column 7, proximate lines 44-50).

Unlike the claimed biofragmentable device, Huebsch in these excerpts is describing a biodegradable coating on the device to assist in its long term placement. Thus, Huebsch fails to teach the claimed combination. Moreover, Applicant respectfully asserts that Huebsch teaches away from a biofragmentable anastomosis devise. First, as a device placed in the cardiac pulmonary system, the device is either allowed to stabilize with tissue ingrowth over a period of time (Col. 7, line 48, Abstract lines 9-12). Given the detrimental risks of embolisms and strokes due to debris in the blood stream, this approach is not surprising. Huebsch thus fails to appreciate the problems unique to an anastomosis between lumens of the gastrointestinal tract. Therefore, there is no suggestion or motivation in the cited references to modify the cardiac device of Huebsch for a GI tract anastomosis device that fragments and passes out of the body.

Reconsideration and allowance of claim 1, as well as claims 2-5 and 8-12 that depend therefrom, is respectfully requested.

Turning to claim 21, the new claim is the originally filed claim 4 rewritten into independent format. The claim recites in part that proximal arms are radially staggered with the distal arms to form a tortuous path of apposed tissue. Thereby tissue damage is avoided due to high pressure contact areas between a corresponding pair of opposing proximal and distal arms.

The Examiner rejected the claimed combination as unpatentable over Huebsch in light of Berg, the latter relied upon as follows: "Berg teaches a device wherein the proximal extending tissue contacting portions (108) are staggered with respect to the distal extending tissue contacting portions (110) as seen in fig. 6 in order to limit tissue damage on both sides of the tissue."

Applicant was unable to locate a suggestion or teaching of Berg that the staggering of the contacting portions 108, 110 were for the purpose of forming a tortuous path between apposed tissue. Instead, Berg is directed to forming a plug within a blood vessel or a defect between lateral chambers of the heart. The frame 102 taught by Berg necessitates some sinusoidal pattern proximal to distal to form the fingers. Applicant suggests that Berg fails to appreciate the problems associate with a pair of thin tissue walls of the GI tract at an anastomosis. Thus, there has not been pointed out a suggestion or motivation in the cited references to modify the device of Huebsch to alternate the proximal and distal arms. Consequently, claim 21 should be allowable, as well as claim 22 that depends from 21 and recites the additional features of originally filed claim 12.

Turning to new claims 23-32, these claims recite methods of making an anastomosis device corresponding to the apparatus claims originally filed as claims 13-29, 11 and 12 respectively obviating a rejection based upon a product by process limitation being anticipated by a product made by another process. In addition, certain claims correspond to apparatus limitations distinguished above.

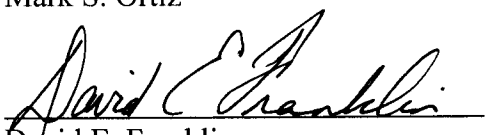
CONCLUSION

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are now in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicant encourages the Examiner to contact their representative David Franklin at 513-651-6856 to answer any questions or concerns.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Account No. 06-2226.

Respectfully submitted,

Mark S. Ortiz



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CERTIFICATE OF MAILING

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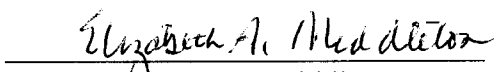

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